tissues in the margin region. Further embodiments of the invention device are provided below.

[0012] Other features and advantages of the invention will be apparent from the following drawings, detailed description, and appended claims.

BRIEF DESCRIPTION OF THE DRAWINGS

[0013] The patent or application file contains at least one drawing executed in color. Copies of this patent or patent application publication with color drawing(s) will be provided by the U.S. Patent and Trademark Office upon request and payment of the necessary fee.

[0014] FIG. **1** is a graph showing wound strength as measured by the breaking point of healing skin samples treated in vivo with saline alone, saline plus electroporation, Bleomycin alone, and Bleomycin plus electroporation. Underlying fat and muscle tissue were also treated in these experiments.

[0015] FIGS. **2**A-F are micrographs of trichrome stained tissues showing comparisons between (A) untreated tissue at day 2 post incision, and (B) tissue treated with saline plus electroporation at day 2 post incision, (C) saline plus electroporation at week 2, (D) Bleomycin plus electroporation at 2 weeks, (E) saline plus electroporation at 3 weeks, and (F) Bleomycin plus electroporation at 3 weeks.

[0016] FIGS. **3**A-D are stained (Trichrome) micrographs of collagen deposition in skin incisions after three weeks. FIGS. **3**A and C are bright field images for Bleomycin and Saline treated skin tissues, respectively, while FIGS. **3**B and C are polarized light images showing Bleomycin and Saline treated skin tissues, respectively.

[0017] FIGS. **4**A-D are micrographs showing samples of muscle tissue at 3 weeks post incision; (A) saline alone, (B) saline plus electroporation, (C) Bleomycin alone, and (D) Bleomycin plus electroporation.

[0018] FIG. **5** is a cross sectional figure of one embodiment of the invention device showing an embodiment comprising a handle comprising a thumb wheel for raising and lowering an array of plungers which actuate loading or dispensing of a substance through the electrode needles.

[0019] FIG. **6** is a drawing depicting an exploded view of one embodiment of the invention.

[0020] FIG. **7** is a cross sectional drawing of one embodiment of the invention device wherein the plungers are actuated by a screw driven by clockwise (raising plungers) and counter clockwise (lowering plungers) rotation of the housing **50**.

[0021] FIGS. **8**A and B are perspective drawings of one embodiment of the invention wherein rotation of the housing **50** will drive the array of plungers back and forth. Figure A shows the embodiment with the tray **20** while Figure B shows the main body of the embodiment without the tray **20**.

[0022] FIG. **9** is a perspective drawing showing one embodiment of the invention wherein the array of plungers is actuated via a wing nut.

[0023] FIG. **10** shows an example of the array of the plurality of electrode needles from the underside of the substrate **22**.

[0024] FIGS. **11** A, B, C, and D are photographs of Group 2 cohort animals showing the test animal with tumor (A), the tumor surgically exposed prior to complete tumor removal (B), the open wound bed after tumor removal but prior to sham EP (C), and the surgical/treatment site after 3 weeks post treatment (D). With this Group 2, no electroporation was performed and the tumor recurred even though the tumor had been completely removed.

[0025] FIGS. **12** A, B, C, and D are photographs of Group 1 cohort animals showing the test animal with tumor (A), the tumor surgically exposed prior to complete tumor removal (B), the open wound bed after tumor removal but prior to treatment with EP (C), and the surgical/treatment site after 3 weeks post treatment (D). As observed with Bleomycin-EP treatment no tumor recurred at the site of treatment.

[0026] FIGS. **13** A, B, and C are photographs of Group 7 cohort animals showing the test animal with tumor (A), after partial tumor removal (B), and the surgical/treatment site after 3 weeks post treatment (C). The mouse at 3 weeks showed no tumor recurrence even though the tumor was only partially removed.

[0027] FIGS. **14** A, B, and C are photographs of Group 4 cohort animals showing the test animal with tumor (A), after partial tumor removal (B), and the surgical/treatment site after 3 weeks post treatment (C). Without EPT the tumor continued to grow.

[0028] FIG. **15** shows a bar graph of the data presented in Table V. PTE refers to partial tumor excision, CTE refers to complete tumor excision, Bi.v. means Bleomycin administered to test animals intraveneously, EP means electroporation, i.t.B refers to Bleomycin administered intratumorally, and PEP means partial electroporation.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0029] As those in the art will appreciate, the following description describes certain preferred embodiments of the invention in detail, and is thus only representative and does not depict the actual scope of the invention. Before describing the present invention in detail, it is understood that the invention is not limited to the particular device arrangements, systems, and methodologies described, as these may vary. It is also to be understood that the terminology used herein is for the purpose of describing particular embodiments only, and is not intended to limit the scope of the invention defined by the appended claims.

Overview

[0030] Electroporation Therapy (EPT), also known as Electrochemotherapy (ECT), is a method to treat localized cancerous lesions and tumor masses. The method comprises administering certain chemotherapeutic drugs, most commonly Bleomycin, either intratumorally or intravenously. In most cases electroporation (EP) is performed by inserting arrays of needle electrodes and delivering pulsed electrical fields emanating from these electrodes directly to the cancerous cell mass. Pulse parameters are generally within the following ranges: field strength 200-2000 V/cm; pulse length 0.1-10.0 ms; pulse number 2-20; and pulse frequency 1-5 Hz. Applying such electric fields results in permeabilization of tumor cell membranes which allows anticancer drugs to enter cells and to cause up to 5000-fold greater cytotoxicity due to the drug uptake than observed in the absence of electroporation. EPT has been shown to be effective against many types of solid tumors in animals and several types of tumors in humans. In fact, several clinical studies are presently ongoing, including a Phase III study evaluating the safety and efficacy of EPT for the treatment of squamous cell carcinomas of the head and neck. How-